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### REMARKS

Claims 5, 8-12, 15, 17-27 and 30-34 are all the claims presently pending in the application. Claims 5, 8, 11, 12 and 15 have been amended to more particularly define the invention.

It is noted that the claim amendments are made only for more particularly pointing out the invention, and not for distinguishing the invention over the prior art, narrowing the claims or for any statutory requirements of patentability. Further, Applicant specifically states that no amendment to any claim herein should be construed as a disclaimer of any interest in or right to an equivalent of any element or feature of the amended claim.

Claim 32 stands rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled by the specification.

Claims 5, 8-12, 15, 17-27 and 30-34 stand rejected under 35 U.S.C. § 103(a) as being anticipated by Dollinger (U.S. Patent No. 5,451,505) in view of Beremand et al. (U. S. Patent No. 4,888,282).

These rejections are respectfully traversed in the following discussion.

#### **I. THE CLAIMED INVENTION**

The claimed invention (e.g., as recited in claim 5, and similarly recited in claims 8, 11, 12 and 15) is directed to DNA having embedded information. The DNA includes a gene portion including a predetermined gene, a portion which is other than the gene portion, and a nucleotide sequence which is not naturally occurring in the DNA and which is embedded in the portion which is other than the gene portion, and includes source identification information which identifies a source of the predetermined gene in the gene portion.

Conventional DNA may include a value-added gene embedded therein, in order to improve the characteristics of the organism having the DNA. However, such conventional DNA does not include any information therein to determine the source of the value-added gene embedded therein. Since DNA having such a value-added gene is easily copied, it is difficult to apply technical restrictions to the copying, by third parties, of value-added genes.

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The claimed invention, on the other hand, includes DNA having a nucleotide sequence which is not naturally occurring in the DNA and which is embedded in the portion which is other than the gene portion, and includes source identification information which identifies a source of the predetermined gene in the gene portion (Application at page 4, lines 5-9; page 11, lines 2-21). This nucleotide sequence may be used to identify the source of genetic information, for example, when the DNA is copied by a third party. Therefore, the claimed invention helps to prevent illegal copying of such genetic information (e.g., a value-added gene).

## II. THE 35 USC §112, SECOND PARAGRAPH REJECTION

Claim 32 stands rejected under 35 U.S.C. §112, first paragraph. Applicant submits, however, that claim 32 is fully enabled by the specification.

Indeed, Applicant would point out that 35 U.S.C. §112, first paragraph requires only that the specification "*enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same*".

Claim 32 recites "*wherein said portion which is other than said gene portion comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence*".

The Application states:

*"The form of the genetic information in a cell will now be described through an explanation of the overview of a process by which [a] gene codes for a protein molecule ... Arranged in the DNA are four bases, A (adenine), T (thymine), G (guanine) and C (cytosine). This sequence of the four bases (hereinafter the bases are referred to by their initials, A, T, G and C) of DNA consists of a gene portion wherein a protein code sequence and its transcription control information are stored, and a portion wherein genetic information is not included"* (Application at page 12, line 24-page 13, line 6) (emphasis added).

That is, the Application defines a gene portion (e.g., in an exemplary aspect) as a portion where a protein code sequence and its transcription control information are stored. Thus, one of

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ordinary skill in the art would likely assume **and it is reasonable to conclude that** a portion other than a gene portion is a portion "*which does not store a protein code sequence and transcription control information for said sequence*", as recited in claim 32.

Thus, the Examiner has failed to show that one of ordinary skill in the art would not know how to make and use the invention.

In view of the foregoing, the Examiner is respectfully requested to withdraw this rejection.

### III. THE ALLEGED PRIOR ART REFERENCES

The Examiner alleges that Dollinger would have been combined with Beremand to form the claimed invention. Applicant submits, however, that these references would not have been combined and even if combined, the combination would not teach or suggest each and every element of the claimed invention.

Dollinger discloses methods for tagging and tracing materials using nucleic acids as taggants. The process of tagging involves altering a substance in a manner that allows for the subsequent identification of the substance by detecting the alteration which involves nucleic acids (Dollinger at Abstract).

Beremand discloses a synthetic gene which encodes for an acyl carrier protein (Beremand at Abstract).

However, Applicant submits that these references would not have been combined as alleged by the Examiner. Indeed, these references are directed to different problems. Specifically, Dollinger is directed to **a taggant (e.g., a nucleic acid) to an item such as radioactive waste in order to identify the source of the item**. That is, Dollinger has nothing to do with genes. Beremand, on the other hand, is directed to **a method of producing a synthetic gene**. Certainly, no person of ordinary skill in the art would have considered combining these references.

Further, Applicant submits that the Examiner can point to no motivation or suggestion in the references to urge the combination as alleged by the Examiner. Therefore, the Examiner has

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failed to make a prima facie case of obviousness.

Moreover, contrary to the Examiner's allegations, neither Dollinger, nor Beremand, nor any combination thereof teaches or suggests "*a nucleotide sequence which is not naturally occurring in said DNA and which is embedded in said portion which is other than said gene portion, and comprises source identification information which identifies a source of said predetermined gene in said gene portion*", as recited in claims 5 and 12 and similarly recited in claims 8, 11, and 15.

With respect to Dollinger, Applicant respectfully submits that Applicant has repeated his arguments over and over to the Examiner but the Examiner continues to ignore Applicant's arguments. Indeed, the Examiner ignored Applicant's arguments included in the **Amendment filed on April 13, 2004** and the **Amendment filed on September 1, 2004**. The Examiner's failure to consider Applicant's arguments necessitated the filing of a **Request for Continued Examination on October 6, 2004**. The Examiner then ignored Applicant's arguments included in the **Amendment filed on March 3, 2005**.

Applicant now sets forth the same arguments now **for at least the fourth time**, and again respectfully requests that the Examiner give them proper consideration. Further, if the Examiner does not find the Application in condition for allowance, Applicant respectfully requests that the Examiner explain in detail where these features are taught in Dollinger.

**A. Dollinger does not teach or suggest a nucleotide sequence that is "*embedded in said portion which is other than said gene portion*"**

First, Applicant has repeatedly pointed out that the taggant in Dollinger could not be considered a nucleotide sequence, but even assuming (arguendo) that the taggant could be considered a "nucleotide sequence", **the taggant in Dollinger is not "embedded in DNA"**, let alone embedded in a portion which is other than a gene portion of DNA (e.g., a portion of DNA which does not include a protein code sequence and its transcription control information). Instead, as noted above, the taggant is applied to the barrel of radioactive waste with a spray bottle.

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However, in the Office Action dated May 9, 2005, the Examiner again ignores this argument. For example, on page 5 of the Office Action the Examiner surprisingly states:

*"Dollinger describes that the nucleic acid may be covalently bound to any one or all of the components of a material comprised of different components (col. 2, lines 19-22) which represents embedding at random locations, as stated in instant claim 22".*

Thus, in spite of Applicant's repeated arguments pointing out that in the claimed invention the nucleotide sequence is **embedded in DNA**, the Examiner surprisingly responds by stating only that the nucleic acid in Dollinger is "covalently bound" to the "material".

Applicant would point out that a covalent bond is a chemical bond in which two atoms share valence electrons. Clearly, a mere "sharing of electrons" does not suggest embedding a nucleotide sequence in a strand of DNA. In the claimed invention, the nucleotide sequence (e.g., the entire nucleotide sequence) is **"embedded in DNA"**, not **"attached to DNA"** (e.g., see Application at Figure 8). Thus, the claimed invention is completely unrelated to the nucleic acid in Dollinger which merely has an atom that shares an electron with an atom of some material.

Further, the "material" to which the nucleic acid is covalently bound is clearly **not DNA**. Instead, the "material" in Dollinger may include "air pollutants, oils, aromatic compounds, explosive compositions, food stuffs, medicaments, inks, paper goods, and paint products" (Dollinger at col. 2, lines 10-14). Dollinger states that the taggant may be applied to a material **by either spraying the taggant onto the surface of the item or physically mixing the taggant and the item** (Dollinger at col. 4, lines 13-19).

Applicant would point out that these "materials" in Dollinger are **not even living organisms** and therefore, do not likely include DNA. Therefore, it is completely unreasonable and absurd to suggest that spraying a nucleic acid onto one of these "materials" is akin to embedding a nucleotide sequence **in DNA**.

Moreover, even assuming (arguendo) that the taggant could somehow be considered a "nucleotide sequence" which is somehow embedded in DNA, Dollinger certainly does not teach or suggest embedding a nucleotide sequence in a particular portion of DNA. That is, Dollinger

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certainly does not teach or suggest embedding a nucleotide sequence in a portion of DNA which is other than a gene portion of DNA (e.g., a portion of DNA which does not include a protein code sequence and its transcription control information) as in the claimed invention.

**B. Dollinger does not teach or suggest a nucleotide sequence "*which identifies a source of said predetermined gene*"**

Second, Applicant has repeatedly pointed out that the taggant in Dollinger is not used to identify the "source of said predetermined gene". Instead, as noted above, the taggant is applied to a material (e.g., a barrel of radioactive waste) to identify the source of the material (e.g., the nuclear power plant that generated the radioactive waste).

However, in the Office Action dated May 9, 2005, the Examiner again ignores this argument. For example, on page 4 of the Office Action the Examiner surprisingly states:

*"Dollinger describes the nucleic acid taggant comprises a specific nucleotide sequence or a composition of specific nucleotides to facilitate tracing or determining the origin or source of a material (col. 1, lines 54-60 and col. 3, lines 7-8) which represents identifying a source and source identification information, as stated in instant claim 5".*

Thus, in spite of Applicant's repeated arguments pointing out that in the claimed invention the nucleotide sequence identifies a source of the predetermined gene, the Examiner surprisingly responds by stating only that the nucleic acid in Dollinger facilitates "determining the origin or source of a material".

Applicant again points out that Dollinger states that "[t]he materials or substances of this invention include those selected from the group consisting of air pollutants, oils, aromatic compounds, explosive compositions, food stuffs, medicaments, inks, paper goods, and paint products" (Dollinger at col. 2, lines 10-14). Therefore, the Examiner is surprisingly attempting to equate the "material" which is tagged with a taggant in Dollinger with a gene.

Applicant respectfully submits that no person of ordinary skill in the art would ever confuse the "predetermined gene" of the claimed invention with the "material" (e.g., an air

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pollutant) which is not even a living organism. Thus, it is completely unreasonable and absurd to suggest that a taggant used to identify a source of non-living material (e.g., radioactive waste) on which the taggant is applied, could teach or suggest a nucleotide sequence which is embedded in a non-gene portion of DNA and **identifies a source of a gene in the gene portion of that DNA.**

Moreover, Applicant would point out that on page 6 of the Office Action, **the Examiner expressly concedes that Dollinger does not teach or suggest a predetermined gene.**

Applicant therefore, states that it is even more unreasonable and absurd to suggest that Dollinger teaches identifying a source of a predetermined gene, since Dollinger does not even teach or suggest a pretermind gene.

Therefore, Applicant again submits that Dollinger does not teach or suggest these novel features. Therefore, Applicant again requests that the Examiner give these arguments proper consideration.

Likewise, neither are these novel features of the invention taught or suggested by Beremand. Indeed, as noted above, Beremand merely discloses a synthetic ACP gene which encodes for acyl carrier protein (ACP). Beremand teaches that the gene may be a component of a larger synthetic recombinant DNA molecule including other DNA sequences (Beremand at col. 5, lines 1-3).

However, **nowhere does Beremand teach or suggest embedding a nucleotide sequence in a non-gene portion of the DNA molecule to identify the source of the ACP gene.** Thus, for example, if Purdue University created a DNA molecule which includes the ACP gene, a person examining the DNA molecule may have no way of knowing that Purdue University was the source of the ACP gene in the DNA molecule.

Therefore, contrary to the Examiner's allegations, Beremand does not make up for the deficiencies of the claimed invention.

Therefore, Applicant submits that these references would not have been combined and even if combined, the combination would not teach or suggest each and every element of the claimed invention. Therefore, the Examiner is respectfully requested to withdraw this rejection.

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#### IV. FORMAL MATTERS AND CONCLUSION

Applicant again respectfully requests that the Examiner consider the documents submitted with the Information Disclosure Statement filed on May 17, 2004, and acknowledge her consideration of the documents in her next Official Communication.

In view of the foregoing, Applicant submits that claims 5, 8-12 and 15, 17-27 and 30-34, all the claims presently pending in the application, are patentably distinct over the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue at the earliest possible time.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephonic or personal interview.

The Commissioner is hereby authorized to charge any deficiency in fees or to credit any overpayment in fees to Assignee's Deposit Account No. 50-0510.

Respectfully Submitted,

Date: 7/29/05

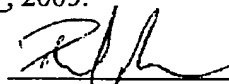


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#### CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing was filed by facsimile with the United States Patent and Trademark Office, Examiner Carolyn Smith, Group Art Unit # 1631 at fax number (571) 273-8300 this 29th day of July, 2005.



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